THE ETHICAL BALANCE BETWEEN INDIVIDUAL AND POPULATION HEALTH INTERESTS TO EFFECTIVELY MANAGE PANDEMICS AND EPIDEMICS

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ABSTRACT

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There is no overlapping criterion providing a basis for attaining balance between individual and population oriented ethical concerns generated in the pandemic and the epidemic interventions. The shortfall leads to competing individual and population interests that hamper the effective management of pandemics and epidemics. The libertarian model focuses on advancing individual rights. The epidemiological model focuses upon population health. The social justice model focuses on a broader perspective than individual rights and population health to include universal human rights.

This dissertation suggests a Mixed Interests Ethics Model (MIEM) to ethically negotiate a balance between the individual and population interests in pandemics and epidemics. MIEM involves a combination of models (libertarian, epidemiological, and

social justice) that shed light on substantive ethical principles of each model (e.g. autonomy, solidarity, and common good); which in turn require procedural standards (i.e. necessity, reasonableness, proportionality, and harm avoidance) to negotiate between the principles when they conflict.

The *UNESCO Universal Declaration on Bioethics and Human Rights* provides a hermeneutical context for applying MIEM in so far as it places MIEM within the context of promoting rights (individual and human) by considering the general ethical tension between individual and universal rights as explained by the UNESCO Declaration.

DEDICATION

This dissertation is dedicated to Reverend Monsignor Joseph Mary Obunga.

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LIST OF ABBREVIATIONS AND ACRONYMS

ABC	Abstain, Be Faithful, or use a Condom
AMA	American Medical Association
ASBH	American Society for Bioethics and Humanities
CAF	Children's AIDS Fund
CAWA	Campus Alliance to Wipe Out AIDS
CDC	Center for Disease Control
CEJA	Council on Ethics and Judicial Affairs of the American Medical Association
CHUSA	Church Human Services AIDS Prevention and Care (Uganda)
CIOMS	Council for International Organizations of Medical Sciences
CPPR	Counterterrorism Planning, Preparedness and Response Act
CS	Cellulose Sulfate (Microbicide Clinical Trial)
HA	Hemagglutinin
HECs	Health Care/Hospital Ethics Committees
HPAs	Health Professional Association Committees
HURINET-U	Human Rights Network Uganda
IBC	International Bioethics Committee of UNECSO
IRB	Institutional Review Board
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
JCAHO	Joint Commission on Accreditation of Healthcare Organizations

IMAU	Islamic Medical Association of Uganda (IMAU)
IPRP	Influenza Pandemic Response Plan
MIEM	Mixed Interest Ethics Model
MSEHPA	Model State Emergency Health Power Act
NA	Neuramidinidase
PA's IPRP	Pennsylvania Department of Health's Influenza Pandemic Response Plan
PEPFAR	President's Emergency Plan for AIDS Relief
PMAs	Policy-making and/or Advisory Committees
PMTCT	Prevention of Mother-to-Child Transmission
RECs	Research Ethics Committees
SECAM	Symposium of Episcopal Conference of Africa and Madagascar
SMC	Safe Male Circumcision
TASO	The AIDS Support Organization
UDBHR	UNESCO's Universal Declaration on Bioethics and Human Rights
UDHR	The Universal Declaration of Human Rights
UNCST	Uganda National Council for Science and Technology (UNCST)
UNESCO	United Nations Educational, Scientific and Cultural Organization
USAID	U.S. Agency for International Development
USPHS	The United States Public Health Services
VA	Department of Veteran Affairs
WHO	World Health Organization
WHO/GPA	World Health Organization/Global Program on AIDS

1. Chapter One

Amelioration of Individual Rights in the Influenza Pandemic Intervention

Introduction

The most problematic public health ethical issue in responses to bioterrorism and pandemics has been identified by scholars, such as Lawrence O. Gostin and colleagues, as the tension between the individual and population interests (common good).[1] Individual health preferences are traditionally well defended in the libertarian-oriented model. Conversely, the epidemiological model is framed on the need to promote and protect population health, and safety. The ethical guide to effectively manage pandemics needs to be based on a criterion that balances between individual and population interests.

A. The Emergence of Influenza Pandemic and Prevention Initiatives

(i) H5N1 Influenza Pandemic and the Population Good

Following the influenza A subtype H5N1 (bird flu) of 2004, the World Health Organization cautioned of a possible mutation of the virus, and, outbreak of a highly pathogenic influenza A pandemic H5N1 virus that could spread between humans. Public health authorities estimate that morbidity and mortality in the United States, within 12-16 weeks, could reach 50 million requiring outpatient care, 2 million requiring hospitalization, and, 500,000 deaths.[2]

A pandemic refers to a disease outbreak affecting the populations of several countries, or continents. The influenza pandemic occurs when a new influenza virus emerges for which people have little or no immunity and for which there is no vaccine.[3]

Since 2003, several governments, worldwide, have undertaken the initiative to put into place influenza pandemic preparedness plans. Even prior to the anticipation of H5N1, in United States, the Center for Disease Control (CDC) had issued the 2001 draft *Model State Emergency Health Powers Act* (MSEHPA) to guide disaster preparedness.[4]

The MSEHPA was drafted to enhance government regulative powers in matters of public health preparedness, surveillance, management of property, protection of persons, and communication.[5] There was a feeling among some policymakers that the existing laws could not adequately provide the necessary authority needed for effective intervention in those five key public health areas. Moreover, states lacked the necessary public health infrastructure for management of pandemics and bioterrorism threats. The experts advanced the Model Act as necessary to strengthen states with the comprehensive powers needed to effectively manage disastrous disease outbreak, while respecting individual rights and freedoms.[6] They justified government exercise of compulsory powers on the basis of the protection and defense of the common good of safety and health.

The MSEHPA encountered significant criticism for endorsing broad government coercive powers to promote and protect population wellbeing, while subordinating individual preferences.[7] Some of the most contentious issues revolve around articles V and VI requiring the use of government regulative powers to carry out mandatory vaccinations, quarantine, involuntary treatment, confiscation of private property, and criminalization of non-compliant individuals.[8] For instance, Article VI, Section 602 (b) states:

> The Public health authority may isolate or quarantine, pursuant to Section 604, any person whose refusal of medical examination or testing results in uncertainty regarding whether he or she has been exposed or is infected with a contagious or possible contagious disease or otherwise poses a danger to the public.[9]

With a pending threat of human-to-human H5N1 in 2004, several states adopted a version of the MSEHPA. The State of Pennsylvania, for instance, introduced a draft titled *Influenza Pandemic Response Plan (IPRP)* in 2005. The IPRP contains an ordinance mandating the governor to declare an emergency for purposes of protecting the health and safety of the Pennsylvania population. The proposed intervention includes possible mandatory measures such as involuntary vaccine, quarantine, and isolation.[10]

The MSEHPA and the IPRP commit to the epidemiological goal of managing disease in populations by utilizing government efficiency and coercive powers to prevail over individual interests so as to do surveillance, effectively plan, coordinate, manage property, and protect populations.[11] This public health paternalism is justified on the basis of protecting the population good of safety and health. Safety and health, in this tradition, constitute community or group compelling interests deserving of protection by health authority over competing individual choices.[12]

The MSEHPA ignited a debate among scholars and health providers concerning priorities between population and individual interests. Authors of the MSEHPA and scholars in the communitarian tradition have since generated considerable amount of literature in defense of the population-good oriented approach. Of foremost relevance is Lawrence O. Gostin and colleagues who explain the fundamental ethical problem of population health as the balancing of the tension between the individual interests and the

common good of health and safety of the population.[13] Gostin articulates the problem that:

> Despite its success in many states, the Model Act has become a lightning rod for criticism from both ends of the political spectrum. Civil libertarians object to the diminution of personal freedoms and conservatives object to the diminution of free enterprise and property rights. In short, the Model Act galvanized public debate around the appropriate balance between personal right and common goods.[14]

Gostin argues that the issue of government compulsory powers over individuals should not focus on whether they are relevant but whether there is balance to safeguard individual rights. He sees the rejection of substantial government presence into people's social lives as symptomatic of a paradigm shift in American values towards individualistic oriented personal freedoms since the early beginning of the 21st Century.[15] Gostin and peers support a legal and ethical framework that utilizes government compulsory powers in circumstances where there is credible belief that the individual will cause undue risk to population health.[16]

(ii) Protection of Individual Rights

Some experts while unopposed to the need for government regulative powers consider the MSEHPA-sanctioned powers as too broad and invasive of individual rights. As observed by Ken Wing, the language of some provisions such as that in Article III takes paternalism to new levels. The article requires mandatory reporting, by providers, of "all potential cause of public health emergencies – within 24 hours."[17] Wing cautions that "Every doctor and every pharmacist would become an enforcement arm of the public

health authority."[18] He is concerned with the protection of confidentiality and privacy rights.

Individual rights advocates countered the population-oriented epidemiological model with the defense of individual autonomy and a right to self-determination.[19] George Annas, probably the most pronounced critic of the MSEHPA, agrees that government has responsibility to plan, coordinate, and communicate with the public but should not compromise civil liberties. He points to state coercive measures to quarantine, to provide mandatory vaccinations and to impose involuntary treatment as unhelpful for purposes of effective intervention policy. In his view, measures that aim at identifying and treating those who have been exposed to the infectious disease are more effective than targeting the public for quarantine.[20]

Griffin Trotter is an outspoken critic of the notion of common good and the subsequent intrusive broad regulative public health measures. He rejects the idea that the moral problem in mass casualty medicine is achieving the balance between individual interests and the common good. Trotter refers to what others call common good as subsets of individual interest and frames the moral problem of public heath intervention as balancing security and liberty. He does not accept the identification of the common good with community interests (corporate interests) that are distinct from those of the individual.[21] For Trotter, the tension is between opposing groups of individual interests. Following this argument, he understands the balancing of the tension in terms of facilitating consensus in deliberative democracy. He advances the *modus vivendi* theory of permission or consent (generated from the procedural principle) to balance power and facilitate compromise.[22]

Trotter shifts the intervention methodology from a defense of corporate social goals to the democratic deliberative procedure that commit to the prima facie norms of avoiding coercion and prioritizing liberty and autonomy. However, majority permission grounded in deliberative democratic procedures provides no firm basis for ensuring just outcomes since in mass casualty medical scientific facts and experience are raw data. Knowledge, which is the primary tool of interpretation in democratic deliberative procedures, is in short supply here. The critics of Trotter point out that ethical decision are primarily sourced from established substantive values, scientific knowledge, and experience.[23]

(iii) Compatibility of Individual Rights with Population Good.

Drawing from this intervention discourse, of strengthening public health powers rather than focusing on deliberative procedures, neither the individual-oriented libertarian model nor the population-oriented epidemiological model singularly provides comprehensive ethical resources for the effective management of pandemics. Dan Beauchamp states that in one version of the democratic theory the individual interests override any restrictions government seeks to impose on the individual apart from avoidance of harm to others.[24] Accordingly, the role of government is "the protection of every individual's private rights."[25]

Reversely, the epidemiological model aligns with a view of democracy that condones government regulative powers, as necessary for "protecting and promoting both private and group interests."[26] Dan Beauchamp elucidates that, in United States, this view of community interests originates from the constitutional tradition. The common citizenship, constituting of divergent views and interests, is presumed to share "sets of loyalties and

obligations to support the ends of the political community."[27] Public health and safety are considered valuable ends meriting societal commitment.

The most common example elucidating the commitment to population good is the 1905 case of Rev. Jacobson of Massachusetts. Jacobson refused to comply with the vaccination law and subsequent penalties following a mandatory vaccination measure by the board of health of the city of Cambridge to contain smallpox. The public health authority imposed the measure as necessary for public health and safety. Jacobson claimed the compulsory vaccination law by the state was an invasion of his liberty since it was arbitrary, oppressive and an assault to his person. He further claimed that the law was "… hostile to the inherent right of every freeman to care for his body and health in such way as to him seems best."[28] The Supreme Court determined that there are circumstances where the individual may be legitimately restrained.[29]

However, despite the unanimity regarding the need to contain individual preferences, apparently none in the epidemiological approach holds Hobbesian totalitarian views of absolute supremacy of the state over the individual. Hobbes regarded individuals as intrinsically selfish and egoistic. In this case, the state is justified to impose its absolute will on the individuals to prevent chaos.[30]

Likewise libertarian approaches do not advocate for anarchy despite the emphasis on individual autonomy; at least not in the sense of Robert Paul Wolff's radical individual autonomy that is incompatible with state authority.[31] According to Wolff, individual moral autonomy as it relates to state authority is the refusal to be ruled. Subsequently he considers anarchy as the only doctrine consistent with autonomy.[32] However, all

libertarian approaches share a sturdy commitment to democratic deliberative procedures as an expression of the individual's autonomous will.

This dissertation negotiates the ethical balance of individual and population interests by considering illustrative substantive principles, as follows: autonomy generated by the libertarian model, and, solidarity generated by the population oriented epidemiological model. But providing depth to this deliberation requires a thorough analysis of the underlying moral and political philosophy fueling the tension between the libertarian and epidemiological approaches.

B. Ethical Challenges and Analysis of the Prevention Models.

(i) The Epidemiological model: Rationing Dilemmas and Coercion

The influenza pandemic intervention highlights the tension between libertarian and epidemiological models due to: (1) acute shortages and rationing dilemma that involve deprivation and prioritization; (2) use of coercive measures, such as mandatory vaccination, that are protective of population health but invasive of individual rights.

The Influenza pandemic outbreak could create new complex challenges such as sudden increase in mortality and morbidity, overwhelming patient surge at health facilities, increased workload for individual staff, and shortages of medical supplies. The need to intervene for containment and treatment could lead to the states mandating the exercise of intrusive powers like isolation, quarantine and civil confinement, which could disrupt civil liberties. Other measures such as prioritization, triage, concerns with staff safety, and suspension of treatment of some non-Influenza pandemic related illnesses could also created a challenge to the ethical duty-to-care.[33]

In clinical practice, the primary ethical responsibility of the health provider is to implement the informed autonomous decision of a competent patient. Tom Beauchamp and colleagues define personal autonomy as, at a minimum, "self-rule that is free from both controlling interference by others and from limitation, such as inadequate understanding that prevent meaningful choice." Courts have often attested to the right to self-determination in medical decisions of a person of adult years.[34] This right associated with the legal doctrine of informed consent is based on the principle of bodily integrity. In 1981, the Supreme Court of United States observed that:

> No right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from all restrain or interference of others, unless by clear and unquestionable authority of law.[35]

The right to refuse medical treatment is held as a constitutionally protected liberty guaranteed under due process clause of the 14th amendment of the U.S. constitution. Due process requires that no person shall be deprived of life, liberty, or property without due process of law. In clinical practice, the specification of the informed consent process requires the patient's access to information, the patient's understanding, and the patient's voluntary choices. Intrusive involuntary measures during a pandemic influenza will present providers in the clinical settings with a new contrasting ethical paradigm for deliberations and deliverance of health care.

The epidemiological model justifies use of government regulative powers to prevent harm, maximize utility, and produce benefits for the good of the health of the population. Because of the focus on populations the epidemiological model utilizes utilitarian,